UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,014	10/12/2005	Yasuaki Ito	Q101066	1924

23373 7590 01/08/2008
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
01/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,014	ITO ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2 drawn to a method of screening a compound or element or a salt thereof that changes the binding property or signal transduction of a G protein-coupled receptor protein to an ionizable metal element or a salt thereof, which comprises using (1) said receptor protein, its partial peptide, or a salt thereof and (2) said metal element or a salt thereof.

Group II, claim(s) 3 drawn to a kit comprising a G protein coupled receptor.

Group III, claim(s) 4 drawn to an undisclosed pharmaceutical that changes the binding or signal transduction of a G protein coupled receptor.

Group IV, claim(s) 5 drawn to an undisclosed prophylactic/therapeutic agent for, wounds, burn, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia, arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, diabetes mellitus, respiratory disturbances, indigestion, cardiac disturbances or hypothyroidism, which comprises an agonist for a G protein-coupled receptor.

Group V, claim(s) 6 drawn to an undisclosed prophylactic/therapeutic agent for hypotonic bladder induced by sensory decrease of the bladder or hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, which comprises an agonist for a G protein-coupled receptor.

Group VI, claim(s) 7 drawn to an undisclosed prophylactic/therapeutic agent for renal dysfunction, pulmonary dysfunction or sensory neuropathy, which comprises an antagonist to a G protein-coupled receptor.

Group VII, claim(s) 8 drawn to an undisclosed prophylactic/therapeutic agent for overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which comprises an antagonist to a G protein-coupled receptor.

Group VIII, claim(s) 9 drawn to method of screening an agonist for a G protein-coupled receptor protein, which comprises assaying an intracellular Ca^{2+} level increasing activity when a test compound or element or a salt thereof is brought in contact with a cell containing said receptor protein.

Group IX, claim(s) 10 drawn to method of screening an agonist for or an antagonist to a G protein-coupled receptor, which comprises using (1) said receptor protein or its partial peptide, or a salt thereof and (2) a compound or element or a salt thereof that changes the binding property of said receptor protein or a salt thereof to an ionizable metal element or a salt thereof.

Group X, claim(s) 11 drawn to a kit for screening an agonist for or an antagonist to a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or a salt thereof, which comprises (1) said receptor protein or its partial peptide, or a salt thereof and (2) a compound or element or a salt thereof that changes the binding property of said receptor protein or a salt thereof to an ionizable metal element or a salt thereof.

Group XI, claim(s) 12 drawn to an undisclosed prophylactic/therapeutic agent for wounds, burn, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia, arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, diabetes mellitus, respiratory disturbances, indigestion, cardiac disturbances or hypothyroidism, which comprises a G protein-coupled receptor.

Group XI, claim(s) 13 drawn to a prophylactic/therapeutic agent for hypotonic bladder induced by sensory decrease of the bladder or hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, which comprises a G protein-coupled receptor protein.

Group XII, claim(s) 14 drawn to a prophylactic/therapeutic agent for, wounds, bum, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia, arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, diabetes mellitus, respiratory disturbances, indigestion, cardiac disturbances or hypothyroidism, which comprises a polynucleotide comprising a polynucleotide encoding a G protein-coupled receptor.

Group XIII, claim(s) 15 drawn to a prophylactic/therapeutic agent for hypotonic bladder induced by sensory decrease of the bladder or hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, which comprises a polynucleotide encoding a G protein-coupled receptor.

Group XIV, claim(s) 16 drawn to a diagnostic agent for wounds, burn, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia, arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, diabetes mellitus, respiratory disturbances, indigestion, cardiac disturbances, hypothyroidism, renal dysfunction, pulmonary dysfunction or sensory neuropathy, which comprises a polynucleotide encoding a G protein-coupled receptor.

Group XV, claim(s) 17 drawn to a diagnostic agent for hypotonic bladder induced by sensory decrease of the bladder, hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which comprises a polynucleotide encoding a G protein-coupled receptor.

Group XVI, claim(s) 18 drawn to a prophylactic/therapeutic agent for renal dysfunction, pulmonary dysfunction or sensory neuropathy, which comprises an antibody to a G protein-coupled receptor.

Group XVII, claim(s) 19 drawn to a prophylactic/therapeutic agent for overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which comprises an antibody to a G protein-coupled receptor.

Group XVIII, claim(s) 20 drawn to a diagnostic agent for wounds, burn, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia, arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, diabetes mellitus, respiratory disturbances, indigestion, cardiac disturbances, hypothyroidism, renal dysfunction, pulmonary dysfunction or sensory neuropathy, which comprises an antibody to a G protein-coupled receptor.

Group XIX, claim(s) 21 drawn to a diagnostic agent for hypotonic bladder induced by sensory decrease of the bladder, hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which comprises an antibody to a G protein-coupled receptor.

Group XX, claim(s) 22 drawn to a prophylactic/therapeutic agent for renal dysfunction, pulmonary dysfunction or sensory neuropathy, which comprises a polynucleotide containing the entire or part of a base sequence complementary to a polynucleotide comprising a polynucleotide encoding a G protein-coupled receptor.

Group XXI, claim(s) 23 drawn to a prophylactic/therapeutic agent for overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which comprises a polynucleotide containing the entire or part of a base sequence complementary to a polynucleotide comprising a polynucleotide encoding a G protein-coupled receptor protein.

Group XXII, claim(s) 24 drawn to a method of screening a compound or its salt that changes the expression level of a G protein-coupled receptor protein to prevent/treat wounds, bum, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia, arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, diabetes mellitus, respiratory disturbances, indigestion, cardiac disturbances, hypothyroidism, renal dysfunction, pulmonary dysfunction or sensory neuropathy, which comprises using a polynucleotide comprising a polynucleotide encoding said receptor protein or its partial peptide.

Group XXIII, claim(s) 25 drawn to a method of screening a compound or a salt thereof that changes the expression level of a G protein-coupled receptor, to prevent/treat hypotonic bladder induced by sensory decrease of the bladder, hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which comprises using a polynucleotide comprising a polynucleotide encoding said receptor protein or its partial peptide.

Group XXIV, claim(s) 26 drawn to a kit for screening a compound or its salt that changes the expression level of a G protein-coupled receptor protein comprising the entire or part of a base sequence complementary to a polynucleotide comprising a polynucleotide encoding a G protein-coupled receptor protein to prevent/treat wounds, burn, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia, arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, diabetes mellitus, respiratory disturbances, indigestion, cardiac disturbances, hypothyroidism, renal dysfunction, pulmonary dysfunction or sensory neuropathy, which comprises a polynucleotide comprising a polynucleotide encoding said receptor protein or its partial peptide.

Group XXV, claim(s) 27 drawn to kit for screening a compound or a salt thereof that changes the expression level of a G protein-coupled receptor protein to prevent/treat

hypotonic bladder induced by sensory decrease of" the bladder, hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which comprises a polynucleotide comprising a polynucleotide encoding said receptor protein or its partial peptide.

Group XXVI, claim(s) 28 drawn to a prophylactic/therapeutic agent for wounds, burn, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia, arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, hard labor, diabetes mellitus, respiratory disturbances, indigestion, cardiac disturbances or hypothyroidism, which comprises a compound or its salt that increases the expression level of a G protein-coupled receptor protein.

Group XXVII, claim(s) 29 drawn to a prophylactic/therapeutic agent for hypotonic bladder induced by sensory decrease of the bladder or hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, which comprises a compound or its salt that increases the expression level of a G protein-coupled receptor.

Group XXVIII, claim(s) 30 drawn to a prophylactic/therapeutic agent for renal dysfunction, pulmonary dysfunction or sensory neuropathy, which comprises a compound or its salt that decreases the expression level of a G protein-coupled receptor .

Group XXIX, claims(s) 31 drawn to a prophylactic/therapeutic agent for overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which comprises a compound or its salt that decreases the expression level of a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or its partial peptide.

Group XXX, claims(s) 32 drawn to a method of preventing/treating wounds, bum, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia, arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, diabetes mellitus,respiratory disturbances, indigestion, cardiac disturbances or hypothyroidism, which comprises administering to a mammal an effective dose of a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequences the amino acid sequence represented by SEQ ID NO" I, its partial peptide, or a salt thereof.

Group XXXI, claims(s) 32 drawn to a method of preventing/treating wounds, bum, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia,

arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, diabetes mellitus,respiratory disturbances, indigestion, cardiac disturbances or hypothyroidism, which comprises administering to a mammal an effective dose of a polynucleotide comprising a polynucleotide encoding a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or its partial peptide.

Group XXXII, claims(s) 32 drawn to a method of preventing/treating wounds, bum, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia, arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, diabetes mellitus,respiratory disturbances, indigestion, cardiac disturbances or hypothyroidism, which comprises administering to a mammal an effective dose of an agonist for a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or a salt thereof.

Group XXXIII, claims(s) 32 drawn to a method of preventing/treating wounds, bum, declining of learning ability, hypogonadism, dysgeusia, anosmia, hyperplasia, arteriosclerosis, myocardial infarction, apoplexy, cirrhosis, cholesterol accumulation, cancer, diabetes mellitus,respiratory disturbances, indigestion, cardiac disturbances or hypothyroidism, which comprises administering to a mammal an effective dose of a compound or its salt that increases the expression level of a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: I, or its partial peptide..

Group XXXIV, claims(s) 33 drawn to a method of preventing/treating hypotonic bladder induced by sensory decrease of the bladder or hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, which comprises administering to a mammal an effective dose of (i) a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, its partial peptide, or a salt thereof.

Group XXXV, claims(s) 33 drawn to a method of preventing/treating hypotonic bladder induced by sensory decrease of the bladder or hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, which comprises administering to a mammal an effective dose of a polynucleotide comprising a polynucleotide encoding a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or its partial peptide.

Group XXXVI, claims(s) 33 drawn to a method of preventing/treating hypotonic bladder induced by sensory decrease of the bladder or hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, which comprises administering to a mammal an effective dose of an agonist for a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or a salt thereof.

Group XXXVII, claims(s) 33 drawn to a method of preventing/treating hypotonic bladder induced by sensory decrease of the bladder or hypotonic bladder induced by postsurgical bladder anesthesia of the pelvic organs, which comprises administering to a mammal an effective dose of a compound or its salt that increases the expression level of a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or its partial peptide.

Group XXXVIII, claims(s) 34 drawn to a method of preventing/treating renal dysfunction, pulmonary dysfunction or sensory neuropathy, which comprises administering to a mammal an effective dose of (i) an antibody to a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, its partial peptide, or a salt thereof, (ii) a polynucleotide comprising the entire or part of a base sequence complementary to a polynucleotide comprising a polynucleotide encoding a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or its partial peptide, (iii) an antagonist to a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or a salt thereof, or (iv) a compound or its salt that decreases the expression level of a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or its partial peptide.

Group XXXIX, claims(s) 35 drawn to a method of preventing/treating overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which comprises administering to a mammal an effective dose of (i) an antibody to a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, its partial peptide, or a salt thereof.

Group XL, claims(s) 35 drawn to a method of preventing/treating overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which

comprises administering to a mammal an effective dose of a polynucleotide comprising the entire or part of a base sequence complementary to a polynucleotide comprising a polynucleotide encoding a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or its partial peptide.

Group XLI, claims(s) 35 drawn to a method of preventing/treating overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which comprises administering to a mammal an effective dose an antagonist to a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or a salt thereof.

Group XLII, claims(s) 35 drawn to a method of preventing/treating overactive bladder-induced pollakiuria, nocturia, cystitis-induced pollakiuria, prostatic hyperplasia-induced pollakiuria, urinary incontinence, urinary urgency, pelvic visceral pain, coital pain, bladder irritation symptoms or various disorders caused by urinary calculus, which comprises administering to a mammal an effective dose of a compound or its salt that decreases the expression level of a G protein-coupled receptor protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, or its partial peptide.

Use claims 36-39 are not grouped because it is not clear what they are claiming.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The G protein coupled receptor used in the claimed methods is not novel (see International Search Report). The special technical feature of the invention resides in the use of specific GPCRs in screening, diagnosis, treatment of specific disease states or its use in specific methods which screen for receptor functionality. Because the special technical feature of the invention resides in the screening method of claim 1, a technical relationship does not exist between the claimed groups.

It has been determined that Groups IV-XLII contain mis-joined Markush groups that encompasses a plurality of independent and distinct inventions which require further restriction. In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may

encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 USC 103.

Groups IV-XLII are drawn to a evaluating or treating a plurality of diseases with different etiologies encompassed by the terms. Evaluating or treating each of the different diseases encompassed by the claims is an independent and distinct invention because no common structural or functional properties are shown to be shared by the diseases. Accordingly, these claims are subject to restriction under U.S.C. 121 and 372. Upon election of Groups IV-XLII, **applicant is additionally required to elect a disease that corresponds to the elected group. This requirement is not to be constructed as a requirement for election of species, since each of the diseases is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.**

The claims of Group IV-XLII are drawn to a multitude of GPCR proteins, (SEQ ID NOs.1, 6 and 8) and methods which use said GPCRs. The claims apply to numerous structurally and functionally different nucleic acids and their encoded polypeptides. This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. Each of the different nucleic acids/polypeptides/antibodies/and methods of use are independent and distinct because no common structural or functional properties are shared. There is no description of the critical feature of the nucleic acid or encoded protein that is required for function. The Markush group contains no conserved regions which is critical to the structure and function of the genus claimed. The common function of the claimed genus of polynucleotides, which is based upon a common property or critical technical feature of the genus claimed is not disclosed. **Accordingly, these claims are subject to restriction. Upon election of Groups of one of groups IV-XLII, applicant is additionally required to elect a single GPCR as it relates to the groups disclosed above. This requirement is not to be constructed as a requirement for election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.**

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nirmal S. Basi
Art Unit 1646

CHRISTINE J. SAOUD
PRIMARY EXAMINER